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[Your Name]

[Your Title]

[Your Company]

[Street Address, City, State ZIP]

May 14, 2026

[Opposing Counsel Name]

[Firm Name]

[Address]

Re: U.S. Patent No. 10792416 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 10792416 (the "10792416 Patent"). After preliminary review, we have substantial concerns about the validity, enforceability, and scope of the asserted claims, summarized below. We reserve all rights and defenses.

1. Subject Patent — Summary

Patent Summary: US 10,792,416 B2

Title: System and method for collecting plasma

Assignee: Haemonetics Corp

Inventor: Michael Ragusa

Filing Date: October 25, 2017

Issue Date: October 6, 2020

Abstract:

A method for collecting plasma includes determining the weight, height, and hematocrit of a donor, and calculating a donor plasma volume and a target plasma collection volume. The target plasma collection volume is based on the donor plasma volume and a target percentage of plasma. The method then withdraws blood from the donor through a line connected to a blood component separation device, and introduces anticoagulant into the withdrawn blood. The blood component separation device...

2. Validity Concerns under 35 U.S.C. § 102 — Prior Art

We have identified prior-art references that, in our preliminary view, anticipate one or more asserted claims of the 10792416 Patent:

Analysis of Prior Art for U.S. Patent 10,792,416

This report provides an analysis of the most relevant prior art for U.S. Patent No. 10,792,416, titled "System and method for collecting plasma." The analysis focuses on identifying prior art that could potentially anticipate the claims of the '416 patent under 35 U.S.C. § 102. The '416 patent, assigned to Haemonetics Corporation, describes a system and method for collecting plasma from a donor by determining the donor's weight and hematocrit, calculating a target plasma collection volume, and then controlling the collection process to obtain a specific volume of "pure plasma" by accounting for the volume of anticoagulant mixed with the collected plasma. Key Innovations in U.S. Patent 10,792,416

The core of the invention in the '416 patent lies in its ability to more accurately determine the actual amount of plasma collected by calculating and subtracting the volume of anticoagulant. This allows for a more precise and individualized plasma collection process, potentially maximizing the yield from each donor while adhering to safety...

3. Obviousness under 35 U.S.C. § 103

Independent of § 102, we believe the asserted claims are obvious in view of combinations of prior art that a person having ordinary skill in the art would have been motivated to combine:

Based on my analysis of US patent 10,792,416 ('416 patent) and the principles of patent law under 35 U.S.C. § 103, the claims of this patent would likely be found obvious in light of a combination of prior art references that existed before the priority date of May 30, 2017.

A person having ordinary skill in the art (POSITA) in the field of apheresis technology would be familiar with automated blood component separation systems, the need to control collection volumes based on donor parameters for safety and regulatory compliance, the fact that collected plasma is mixed with anticoagulant, and the importance of managing a donor's fluid balance.

The following analysis outlines potential combinations of prior art that would render the independent claims of the '416 patent obvious.

Obviousness of Claim 1 (Method) and Claim 11 (System)

Claim 1 describes a method of stopping plasma collection based on a calculated pure plasma volume, where the target is based on donor weight. Claim 11 describes the system with a controller that automates this method. Both are addressed by the same...

4. Litigation History of the Patent

Public records reflect that the 10792416 Patent has been the subject of the following litigation, which informs our view of the asserted claims and your client's enforcement posture:

- Haemonetics Corporation v. Terumo BCT, Inc. — 1:25-cv-01409 · United States District Court for the District of Colorado · filed 2025-05-05 · Ongoing
- Haemonetics Corporation v. Fresenius Kabi USA, LLC et al. — 1:25-cv-08680 · U.S. District Court for the Northern District of Illinois · filed 2025-07-25 · active
- Terumo BCT, Inc. v. Haemonetics Corp. — IPR2025-01420 · U.S. Patent and Trademark Office's Patent Trial and Appeal Board · filed 2025-10-09 · active

5. Request

In light of the foregoing, we request that your client (i) provide a detailed claim chart identifying each accused product or service and mapping every limitation of each asserted claim, (ii) identify any prior art known to your client, including any references cited during prosecution or reexamination, and (iii) substantiate the basis for any damages or licensing demand. We are prepared to discuss the matter further once we have received and reviewed the foregoing.

Sincerely,

[Your Name]

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